K001288

JUL 2 0 2000

Appendix A

510(k) Summary

K001288

The NorthEast Monitoring, Inc. DR180-II Digital Holter Recorder is a redesign of the predicate device, the NorthEast Monitoring, Inc. DR180 Digital Holter Recorder (510(k) K960925). A Holter recorder is used for ambulatory monitoring of 2- or 3-channels of patient ECG. This monitoring is not real-time or telemetry, but is recorded for 24 or 48 hours for later playback and analysis. A Holter recorder allows a patient to leave a hospital or clinical environment, perform all of his / her daily routines, and review the data retrospectively to determine any correlation between symptoms and clinical findings.

CompactFlash™ technology and smaller, more efficient components have allowed the recorder to become smaller and lighter, while providing greater feedback and flexibility to the operator.

The ECG data recorded on the CompactFlash™ card will be analyzed by the *Holter for Windows*® Holter Analysis System (510(k) K930564), as is the ECG data from the predicate device DR180.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2000

Rodney L. Cambre
Director of Regulatory Affairs
NorthEast Monitoring, Inc.
730 Boston Post Road
Suite 23
Sudbury, MA 01776

Re: K001288
DR180 II Holter Recorder
Regulatory Class: II (two)
Product Code: 74 MWJ
Dated: April 21, 2000
Received: April 24, 2000

Dear Mr. Cambre:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K001288

Device Name: DR180-II

Indications For Use:

1. Detection of Arrhythmias: The NorthEast Monitoring, Inc. DR180-II is indicated for use in continuous monitoring of cardiac rhythm when intermittent arrhythmia are suspected due to patient symptoms such as palpitations, transient ischemic attacks (TIAs), syncope (fainting), or other such symptoms as determined by the physician.

2. Efficacy of Treatment: The NorthEast Monitoring, Inc. DR180-II is indicated for use to determine whether current pharmacological treatment(s) of known arrhythmia is effective by measuring the frequency and duration of the arrhythmia compared to the frequency and duration prior to treatment.

3. Pacemaker Evaluation: The NorthEast Monitoring, Inc. DR180-II is indicated for use to evaluate the function of implanted pacemakers to insure that the pacemaker is functioning within prescribed limits.

4. The NorthEast Monitoring, Inc. DR180-II is to be used only by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001288

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)